

has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:

(1) NVLAP-accredited testing laboratory; or

(2) ONC-ATCB when:

(i) Certifying previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s); or

(ii) Performing gap certification.

(i) Submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results; and

(j) Promptly refund any and all fees received for:

(1) Requests for certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Certifications that will not be completed as a result of its conduct; and

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Module(s);

(k) Ensure adherence to the following requirements when issuing a certification to a Complete EHR and/or EHR Module(s):

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is [specify Edition of EHR certification criteria] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services";

(ii) The information an ONC-ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue; and

(iii) Any additional types of costs that an EP, EH, or CAH would pay to implement the Complete EHR's or EHR

Module's capabilities in order to attempt to meet meaningful use objectives and measures. EHR technology self-developers are excluded from this requirement.

(2) A certification issued to a pre-coordinated, integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

[76 FR 1325, Dec. 7, 2011, as amended at 76 FR 72642, Nov. 25, 2011; 77 FR 54291, Sept. 4, 2012]

§ 170.525 Application submission.

(a) An applicant for ONC-ACB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC-ACB status may be submitted to the National Coordinator at any time.

§ 170.530 Review of application.

(a) *Method of review and review timeframe.*

(1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.